UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

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| DEPUY ORTHOPAEDICS, INC., | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | CAUSE NO. 3:12-CV-299-CAN |
| | ) | |
| ORTHOPAEDIC HOSPITAL, | ) | |
| | ) | |
| Defendant. | ) | |

**OPINION AND ORDER**

In this consolidated action, which incorporates both patent and contract claims, Defendant, Orthopaedic Hospital ("the Hospital"), has alleged that Plaintiff, DePuy Orthopaedics, Inc. ("DePuy"), infringed U.S. Patent No. 8,658,710 ("the '710 Patent") and U.S. Patent No. 8,796,347 ("the '347 Patent"). On October 13, 2015, this Court held a claim construction hearing pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996) regarding the two Patents and the following related patent applications: U.S. Patent Application No. 14/262,553 ("the '553 application"); U.S. Patent Application No. 14/489,069 ("the '069 application); and U.S. Patent Application No. 14/566,084 ("the '084 application).

Notably, two of the patent applications have issued as patents since the *Markman* hearing. The '084 application issued to the Hospital as U.S. Patent No. 9,155,817 ("the '817 Patent") on October 13, 2015.[1] In addition, the Hospital has informed the Court that the parties received notice that the United States Patent and Trademark Office ("PTO") has allowed the '553 application to be issued as a patent and closed prosecution on the application's merits as of

[1]At the *Markman* hearing, the parties informed the Court that one of the patent applications had issued since the parties had completed their claim construction briefs. Through independent research of public patent records, the Court learned that the USPTO issued the '084 application as the '817 Patent.

November 13, 2015. *See* Doc. Nos. 161, 161-1, and 161-2. To date, no patent number has been assigned. Moreover, the parties have neither raised any infringement or invalidity contentions related to the new patents nor asked the Court to construe any patent claims from the new patents. Therefore, the Court will address only the construction of claims in the '710 and '347 Patents and the '553, '069, and '084 applications as identified by the parties in their claim construction briefs and at the *Markman* hearing.

Having reviewed the parties' written and oral arguments, the Court issues the following opinion and order regarding the disputed patent claim terms pursuant to the consent of the parties and 28 U.S.C. § 636(c).

## I. THE PATENTS

The technology at issue in this consolidated action involves orthopaedic biomaterials, specifically polyethylene materials used in orthopaedic implants. The '710 and '347 patents (collectively "the Patents"), both entitled "Oxidation-Resistant and Wear-Resistant Polyethylenes for Human Joint Replacements and Methods for Making Them," relate to ultra-high molecular weight polyethylenes ("UHMWPE"), a common plastic used regularly for making components of artificial joints. The Patents were developed to address the problems of wear and oxidation resulting from the normal use of these implants. The '553, '069, and '084 applications share the same specification as the '710 Patent.

To teach the Court about the polyethylene technology involved in the Patents and the three related patent applications, the parties provided a tutorial to the Court immediately preceding the *Markman* hearing in October 2015. Based on the tutorial and the parties' briefing, the Court summarizes the technology and relevant scientific matters involved in this case.

UHMWPE implants are used to treat patients with joint degeneration. Such treatments include total hip and knee replacement surgeries. In a hip replacement surgery, for example, the surgeon replaces the damaged portions of the hip joint with artificial parts designed to function like the original joint. The surgeon removes the damaged surface of a hip socket and inserts an artificial socket, called the acetabular component or cup. The surgeon then removes the head of the femur and hollows out the top of the femur before placing a metal rod, or femoral stem, into the bone. The surgeon attaches a ball to the rod and places the femur into the new socket.

Because the femoral ball is in constant movement within the hip socket cup, various materials, including polyethylene, have been used to line the cup to facilitate movement. However, wear of those polyethylene components can be a significant problem. Wear causes deterioration of the components and releases debris particles inside the body, which can lead to inflammation and loosening of the artificial joint components and even bone deterioration. Oxidation of the polyethylene further contributes to degradation and wear. Therefore, researchers have sought to develop a polyethylene material that is wear-resistant over time while maintaining important qualities such as fatigue strength, fracture toughness, and shear toughness.

One method used to improve wear resistance has been irradiation. Exposure to radiation causes crosslinking, or an increase in the number of bonds between molecules, in the polyethylene material. Radiation is also used to sterilize the polyethylene materials. However, irradiation has unwanted side effects. Specifically, irradiation generates free radicals that bond with oxygen molecules they encounter in the air before implantation or in the body after implantation. Such oxidation, similar to rust, causes pitting, delamination or separation into layers, and fracture of the polyethylene implants.

Prior art teaches methods to minimize the risk of oxidation caused by radiation. For instance, U.S. Patent No. 5,577,368 describes a method of irradiating polyethylene implants in a container pressurized with an inert gas and/or hydrogen to improve oxidation-resistance. U.S. Patent No. 5,753,182 describes a method of subjecting a packaged and irradiated implant to pressured hydrogen gas to reduce free radicals. Other prior art teaches that oxidation can be minimized with thermal treatments, such as annealing or remelting, that extinguish free radicals during or after irradiation. Annealing occurs when the material is heated but not to the point of melting, which occurs at about 155°C. Remelting occurs above the melting point of the material. Unfortunately, thermal treatments also weaken the polyethylene material, once again increasing the wear-resistance problem.

The patents and applications at issue in this case teach that an implant can be rendered oxidation-resistant by adding one or more antioxidants, such as Vitamin E, to the polyethylene. The antioxidant scavenges free radicals and stabilizes them, preventing them from bonding with oxygen. As a result, the implant can be irradiated at a higher dose than typically used for conventional sterilization so as to increase crosslinking and improve wear resistance. Moreover, the antioxidant eliminates the need for a thermal treatment to extinguish free radicals created by the irradiation, which avoids weakening and deforming the implant through heating. Indeed, the alleged invention of the patent claims at issue here is the omission of any thermal treatment step in making a polyethylene implant with a radiation dose above 5 Mrads. The prohibition of a thermal treatment step became the focal point of the Patents' prosecution history and was the basis upon which the PTO allowed the claims to be patented.

## II. PROSECUTION HISTORY

The application that led to the ‘347 patent was filed on October 25, 2002. The application that led to the ‘710 patent was filed on May 24, 2007. The ‘710 Patent was prosecuted for almost seven years, while the ‘347 Patent was prosecuted for almost twelve years. Notable and relevant in those prosecutions were the following key events.

Through its patent applications, the Hospital initially attempted to claim broadly a method of irradiating an oxidation-resistant implant at a radiation dose higher than a standard sterilization dose. The initial claims did not include an antioxidant and did not include any prohibition against performing a thermal treatment. The Examiner rejected those claims.

In an amendment dated July 7, 2008, the Hospital amended the claims to recite that the implant contains an antioxidant and to require that the irradiated implant is not annealed or remelted. The Hospital also amended the claims to include limitations related to degree of swelling, molecular weight between crosslinks, and gel content—all measures of the amount of crosslinking. Despite these amendments, the Hospital’s claims were still rejected.

In August 2013, the Examiner specifically rejected the claims based on a combination of U.S. Patent No. 6,355,215 (“Poggie”) and U.S. Patent No. 6,277,390 (“Shaffner”). The claims then pending prohibited “annealing or melting the irradiated implant before or subsequent to being irradiated,” and the Examiner determined that Poggie taught “heating . . . to an elevated temperature below its annealing temperature (thus not annealed or melted or molten) . . . .” Doc. No. 147-7 at 83.

Following the rejection, the Hospital participated in two interviews with the Examiner. Thereafter, the Hospital again amended the claims and submitted a declaration from Dr. Harry McKellop, one of the named inventors. In its amendment, the Hospital replaced the limitation

"without annealing or remelting the irradiated implant before or subsequent to being irradiated" with the phrase "without thermally treating the implant to extinguish free radicals in the irradiated and crosslinked implant during or subsequent to irradiating the oxidation-resistant implant." *Id.* at 87. The Hospital made this amendment to "eliminate any possible question" about the meaning of the terms "anneal" or "annealing" as previously used in the claims. *Id.* at 98–99. The Hospital also incorporated the prohibition of any "thermal treatment to extinguish free radicals" into all independent claims in their '553, '069, and '084 applications.

In his Declaration, McKellop argued that Poggie taught use of a thermal treatment—a heat treatment below the "annealing temperature"—that was prohibited by the amended claims. Doc. No. 147-9 at 5–6. The prior claim language prohibiting "annealing or remelting" created confusion vis-à-vis Poggie because Poggie did not call its thermal treatment "annealing," and because some skilled artisans used the term "annealing" to refer to heat treatments above 110°C. *Id.*; Doc. No. 147-7 at 98–99. The new claim language thus eliminated this ambiguity making the Poggie low-temperature annealing (*i.e.*, heating below the 100°C ideal annealing temperature) a prohibited thermal treatment outside the scope of the amended claim.

In his Declaration, McKellop further explained that various low-temperature "annealing" steps in other prior art would constitute "thermal treatments to extinguish free radicals" and therefore, would be prohibited by the amended claims. *See* Doc. No. 147-9 at 5, ¶ 16. McKellop stated that "this new language [*i.e.*, the amended claim language] would be understood by the skilled artisan in the context of the disclosure of this patent application to mean without heating the polyethylene to a temperature and for a duration that is sufficient to extinguish free radicals by more than a trivial amount." *Id.* at 6, ¶ 19. In other words, a process using even such low-

temperature annealing steps would be outside the scope of the amended claims.

McKellop cited several examples of low-temperature annealing prohibited by the amended claims. McKellop specifically cited to the method reported in a scientific journal article by polymer scientist Robert M. Streicher, which involved annealing UHMWPE for two hours at temperatures varying between 40 and 80°C. *Id.* at 55.[2] In addition, McKellop cited to U.S. Patent 5,414,049 ("Sun"), which taught two steps of annealing to reduce free radicals. *Id.* The first annealing step was conducted while the polyethylene was still in bulk form and elevated the polyethylene's temperature to 25–140°C, but preferably between 37 and 135°C, for a prescribed time. *Id.* The second annealing step was conducted on the final, packaged implant at a preferred temperature of 37–70°C. *Id.* McKellop then cited other prior art, including two journal articles and U.S. Patent No. 6,228,900 ("Shen"), as further examples of annealing well below the melt temperature as used in Poggie. *Id.* at 55–56.

In December 2014, after both the '710 and '347 Patents were issued with the amended claim, DePuy filed petitions for *inter partes review* ("IPR") with the Patent Trial and Appeal Board ("PTAB") pursuant to 35 U.S.C. § 314. On July 16, 2015, the PTAB denied both petitions finding that DePuy had not "established a reasonable likelihood of prevailing with respect to any of the challenged claims of the '710 patent" as statutorily required for IPR. Doc. No. 147-10 at 3 (citing 35 U.S.C. § 314(a)). In reaching this decision, however, the PTAB construed "the negative limitation [in the '710 Patent] of 'without thermally treating the implant . . .' to preclude either annealing or remelting, both during and after irradiation." *Id*. at 8. The

[2]McKellop attached a reprint of the Streicher article as Exhibit 2 to his Declaration. Doc. No. 147-9 at 43–53. The Streicher article, entitled *Investigation on Sterilization and Modification of High Molecular Weight Polyethylenes by Ionizing Irradiation*, was published in the journal "beta-gamma" in January of 1989.

PTAB also found that DePuy had not "established that a person of ordinary skill in the art would have had a sufficient reason, at the time of the invention, to irradiate the polyethylene implant material taught in the prior art at a radiation dose above 5 Mrad without also thermally treating the implant during or after the irradiation step." *Id.* at 12.

## III. LEGAL STANDARD GOVERNING CLAIM CONSTRUCTION

"Claims define the subject matter that, after examination, has been found to meet the statutory requirements for a patent. Their principal function, therefore, is to provide notice of the boundaries of the right to exclude and to define limits . . . ." *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1347 (Fed. Cir. 2010) (internal citations omitted); *see also Markman*, 517 U.S. at 373. Courts interpret patent claims as a matter of law. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc); *see also Markman*, 517 U.S. at 388–91. Claim terms usually receive their ordinary and customary meaning. *Id.* This is the meaning "as understood by a person of ordinary skill in the art in question at the time of the invention when read in the context of the specification and prosecution history." *Laryngeal Mask Co. v. AMBU A/S*, 618 F.3d 1367, 1370 (Fed. Cir. 2010).

Claim construction begins with consideration of the intrinsic evidence, which includes the patent claims, specification, and prosecution history. *Phillips*, 415 F.3d at 1313. Review of the intrinsic evidence begins with the claims themselves, which provide guidance as to the meaning of claim terms through context and comparisons to other claims. *Id*. at 1314. The patent's specification also informs claim construction as "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Id*. at 1316 (citation omitted). However, interpreting claims

"in light of the specification does not mean that everything expressed in the specification must be read into all the claims." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1326 (Fed. Cir. 2002). Courts should be careful to avoid "import[ing] limitations from the specification into the claims." *CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1231 (Fed. Cir. 2005). Nor should a court "limit[] the claimed invention to preferred embodiments or specific examples in the specification," unless there is a clear statement limiting the scope of the claims in the patent's specification. *Falana v. Kent State Univ.*, 669 F.3d 1349, 1355 (Fed. Cir. 2012).

"In addition to consulting the specification . . . a court should also consider the patent's prosecution history, if it is in evidence." *Phillips*, 415 F.3d at 1317 (internal quotation omitted). "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.* In other words, a patentee cannot recapture through claim construction that which was disclaimed during prosecution. *See, e.g., Omega Engr'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323–24 (Fed. Cir. 2003).

If the court cannot construe the patent claims based only on the intrinsic evidence, it may consider extrinsic evidence, including dictionaries, learned treatises, and expert testimony, to assist it in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Phillips*, 415 F.3d at 1318. Extrinsic evidence may include a PTAB decision regarding IPR, but the court "owes no deference to the PTAB's claim construction done as part of an inter partes review." *Pragmatus AV, LLC v. Yahoo! Inc.*, No. C-13-1176 EMC, 2014 WL 1922081, at *4 (N.D. Cal. May 13, 2014).

## IV. CONSTRUCTION OF THE RELEVANT CLAIMS

The '710 and '347 Patents, assigned to the Hospital by the inventors, Drs. Harry A. McKellop and Fu-Wen Shen, and the '553, '069, and '084 patent applications are all related and have been presented to the Court for construction of several disputed claim terms. The need for claim construction of disputed terms in the existing patents, which have allegedly been infringed and are allegedly invalid, is clear under *Markman* and its progeny. The question of whether claim construction is necessary, or even proper, for the disputed claims in the patent applications is less clear and may even present a question of first impression for this Court. Therefore, the Court will address the propriety of claim construction related to patent applications before construing the disputed claim terms in the '710 and '347 Patents.

### A. Construction of Disputed Terms in Patent Applications

Part of this case is the resolution of a royalties dispute between the parties based on allegedly royalty-bearing products ("AOX") manufactured and sold by DePuy. The parties' license agreement, which is at issue in this litigation, defines royalty-bearing products as those covered by any of the Hospital's patents or patent applications. Because the disputed claims terms in the Patents and patent applications will be involved in resolving both the contractual question of whether DePuy owes the Hospital royalties and the patent law question of whether DePuy infringed the Hospital's Patents, DePuy argues that the unissued claims of the '710 and '347 Patents as well as the claims of related patent applications are relevant to this case and must be construed to facilitate full resolution of the parties' disputes.

According to DePuy, claim construction "is required for a contract case, just as it is for a patent infringement case." Doc. No. 129 at 4. Indeed, this case will require a determination as

to whether DePuy sold products in contravention of the Hospital's exclusive rights to such sales under the license agreement. For the Hospital to succeed on its contract claim and collect royalties, it will need to show that the accused products were covered by the Patents or patent applications.

Courts have already held that putting a patent into a contract does not turn it into a contract term immune from claim construction under *Markman*. In a case where a license agreement provided for royalties on products covered by licensed patents, the Federal Circuit stated:

> The license agreement between Dray and U.S. Valves gives U.S. Valves "an exclusive right to manufacture, use, sell, advertise, and distribute the Licensed Product." To show that Dray sold valves in contravention of U.S. Valves' exclusive rights to such sales, U.S. Valves must show that Dray sold valves that were covered by the licensed patents. Since some of the valves that Dray sold were of the sliding ring variety, a court must interpret the patents and then determine whether the sliding ring valve infringes these patents. Thus patent law is a necessary element of U.S. Valves' breach of contract action.

*U.S. Valves, Inc. v. Dray*, 212 F.3d 1368, 1372 (Fed. Cir. 2000). Another court found it necessary to construe two patent claims because "the trier of fact [would] be unable to determine whether the products on which no royalties [had] been paid [were] covered by the license." *Advanced Card Techs. LLC v. Versatile Card Tech., Inc.*, 410 F. Supp. 2d 158, 160 (S.D.N.Y. 2006). Notably, however, neither DePuy nor the Hospital has located a case that specifically requires claim construction of disputed claims in patent applications. Put another way, no precedent has been found that would require the Court to construe claims in patent applications to resolve a contract dispute. The only clear precedent on claim construction is *Markman*, which only addressed the construction of patent claims included in issued patents. *See Markman*, 517 U.S. at 986–87.

Moreover, claims in patent applications are not subject to 35 U.S.C. § 112(b)'s definiteness requirement, leaving DePuy without any indefiniteness defense to the Hospital's claim for royalties under the license agreement based on the patent applications. Similarly, there is no such thing as an invalidity challenge to claims in patent applications. As a result, the claims in the Hospital's patent applications are merely contract terms defining the scope of royalties under the parties' license agreement. The parties' disagreement over the meaning of those claims may establish ambiguity in the parties' contract terms. But if so, the Court's analysis changes dramatically. For while it is the unquestioned province of the Court to determine disputed terms in patent litigation since *Markman*, it is for the jury alone to determine disputed terms in contract litigation.

"Under Indiana contract law, interpretation of an unambiguous contract is a matter of law that can be resolved on summary judgment." *Automation By Design, Inc. v. Raybestos Prods. Co.*, 463 F.3d 749, 753 (7th Cir. 2006). "Ambiguous contracts, on the other hand, must be set before a trier of fact to ascertain the facts necessary to construe the contract." *Id.* As a result, any ambiguity in patent applications that will be determinative in resolving a dispute over the terms of a license agreement are properly resolved by a trier of fact, not through claim construction by the Court.

With that said, the Court acknowledges DePuy's concerns about inconsistent results arising from the somewhat parallel proceedings of claim construction on the disputed Patent claims by the Court and contractual interpretation of the similarly worded claims in the patent applications by a trier of fact. The risk of inconsistent results, however, can easily be mitigated or possibly even eliminated through procedural mechanisms inherent in litigation, including

motions for summary judgment, motions in limine, jury instructions, ongoing settlement negotiations, or even waiver of a jury demand in favor of a bench trial. Accordingly, the risk of inconsistent results does not tip the scale to persuade the Court to construe claim terms in patent applications. Nor may the Court displace the trier of fact in its role related to the interpretation of ambiguous contracts. In addition, even if the Court did construe claims in the patent applications, those claims could still be amended during the patent prosecution process, mooting any constructions this Court made. Therefore, lacking any precedent that compels claim construction related to patent applications, this Court will only construe disputed claim terms incorporated into issued patents and will not construe the following disputed claim terms found only in the Patent Applications:

(1) "without annealing or melting the irradiated [and crosslinked] implant/the implant is not melted or annealed after the irradiation step" found only in the unissued Claim 2 of patent applications;[3]

(2) "highly resistant to oxidation" found only in Claim 2 of the '084 patent application; and

(3) "total radiation dose" found only in Claim 2 of the '069 patent application.

**B. Patents-in-Suit: the '710 Patent and the '347 Patent**

The '710 patent issued to Drs. Harry A. McKellop and Fu-Wen Shen on February 25, 2014. The '347 patent, which is related to the '710 patent and shares the same title and named inventors, issued on August 5, 2014. Disputed claims terms are found in Claims 1, 2, and 16 of both the '710 and '347 Patents and in Claim 12 of the '347 Patent. Each claim appears in full below with disputed terms underlined.

[3]This disputed claim term comes from the unissued Claim 2 found in the applications that ultimately became the '710 and '347 Patents. Claim 2, after successful amendment, became Claim 1 in both the '710 and '347 Patents. Claim 1 of both Patents will be construed *infra* because the parties dispute its meaning.

**‘710 and ‘347 Patents[4]**

**CLAIM 1**

A method for producing a wear-resistant and oxidation-resistant medical implant of a joint prosthesis, said method comprising the steps of:

(I) providing an oxidation-resistant medical implant of a joint prosthesis comprising a polyethylene component; and

(II) irradiating the oxidation-resistant medical implant at a radiation dose of above 5 Mrad to about 25 Mrad so as to crosslink the implant thereby improving its wear resistance, without thermally treating the implant to extinguish free radicals in the irradiated and crosslinked implant during or subsequent to irradiating the oxidation-resistant implant; wherein the oxidation-resistant implant contains an antioxidant rendering it resistant to oxidation caused by free radicals generated by the irradiation of step (II)[; and the irradiated oxidation-resistant implant possesses the characteristics of: a degree of swelling of between about 1.7 to about 3.6; a molecular weight between crosslinks of between about 400 to about 3,500 g/mol; and a gel content of between about 95% to about 99%].

Doc. No. 147-1 at 12 (‘710); 147-2 at 13 (‘347).

**CLAIM 2**

The method of claim 1, wherein the radiation dose is from above 5 Mrad to about 10 Mrad.

Doc. No. 147-1 at 12 (‘710); 147-2 at 13.

**CLAIM 16**

The method of claim 1, wherein oxidation-resistant medical implant is irradiated at a radiation dose of above 10 Mrad to about 25 Mrad.

Doc. No. 147-1 at 13; 147-2 at 14.

**‘347 Patent**

**CLAIM 12**

The method of claim 1, wherein providing an oxidation-resistant medical implant comprises:

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[4]Claims 1, 2, and 16 of both the ‘710 and ‘347 Patents are identical except that Claim 1 of the ‘347 Patent does not include the material characteristic limitations included at the end of the Claim 1 in the ‘710 claim. The material characteristic limitations are not at issue here but are bracketed for clarity.

either (a) mixing the anti-oxidant polyethylene powder and fusing the mixture to produce an oxidation-resistant preformed polyethylene and machining the oxidation-resistant implant from the oxidation-resistant preformed polyethylene

or (b) mixing the anti-oxidant and the polyethylene powder and fusinig the mixture in a mold to produce a direct molded oxidation-resistant medical implant; and packaging the oxidation-resistant implant in a sealed package.

Doc. No. 147-2 at 14.

**1. "medical implant" / "implant"**

The Hospital contends that both "medical implant" and "implant," as used in Claim 1 of both the '710 and '347 Patents as well as Claim 12 of the '347 Patent, have a plain and ordinary meaning to one of ordinary skill in the art and need not be construed. A construction stating that the "plain and ordinary meaning" should apply may be appropriate when the meaning is "readily apparent even to lay judges" and when claim construction "involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips*, 415 F.3d at 1314, 1327. "[T]he ordinary and accustomed meaning of a disputed claim term is [generally] presumed to be the correct one . . . ." *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1362–63 (Fed. Cir. 1999) (citations omitted). The plain and ordinary meaning will, however, be overcome if a different meaning is clearly and deliberately set forth in the intrinsic record. *Id.* at 1363. Similarly, "if the ordinary and accustomed meaning of a disputed term would deprive the claim of clarity, then further reference must be made to the intrinsic—or in some cases, extrinsic—evidence to ascertain the proper meaning." *Id.* "In either case, a party wishing to alter the meaning of a clear claim term must overcome the presumption that the ordinary and accustomed meaning is the proper one, demonstrating why such an alteration is required." *Id.*

In this case, DePuy contends that both terms should be construed because the plain and

ordinary meaning is broad and inconsistent with the intrinsic record. As a result, DePuy asks the Court to construe both terms as "a finished article suitable for use in an artificial joint prosthesis." DePuy's arguments, however, are brief and unconvincing. DePuy relies predominantly on the specification, which states:

> This invention also presented finished articles (i.e., end products) made of polyethylenes. Non-limiting examples of these finished articles are medical implants.

Doc. No. 147-1 at 6, '710 Patent 4:38–41. DePuy also notes that its proposed construction draws on language found in Claim 1 of the '710 Patent, which states:

> A method for producing a wear-resistant and oxidation-resistant medical implant of a joint prosthesis . . . .

*Id.* at 12.

The Court recognizes the sources for DePuy's proposed construction. Yet, it does not see why DePuy's proposed construction is necessary. As the Hospital notes, the use of the terms in the patent claims is consistent with the intrinsic evidence. For instance, the Hospital cites the Patent Abstracts and multiple references in the specifications that make it obvious that the claim terms "medical implant" and "implant" refer to items made of UHMWPE that are ultimately implanted or placed into human bodies, including but not limited to artificial joint prostheses such as an acetabular cup. *See* Doc. No. 145 at 15–16 (providing multiple citations from the Abstracts and specifications). And even assuming that DePuy can overcome the Hospital's arguments, DePuy's proposed construction is simply an alternative construction that may also be supported by the intrinsic evidence, but is insufficient to show that its construction is necessary to ensure consistency and clarity in light of the intrinsic evidence. *See K-2 Corp.*, 191 F.3d at 1363.

In addition, the Hospital points to extrinsic evidence, including DePuy's own '508 patent and a definition from the American Heritage Dictionary, in support of the plain and ordinary meaning of these terms. Given the strength of support in both the intrinsic and extrinsic evidence for the plain and ordinary meaning of these claim terms, DePuy has not overcome the presumption in favor of the plain and ordinary meaning. Therefore, the Court rejects DePuy's proposed construction of the claim terms "medical implant" and "implant." The plain and ordinary meaning of both terms, as consistent with how a person of ordinary skill in the art would interpret these terms at the time of the invention, will govern as required going forward.

**2. "a radiation dose" / "the radiation dose"**

As quoted in full above, Claims 1 and 16 of both the '710 and '347 Patents use the term "a radiation dose," while Claim 2 of both Patents uses the term "the radiation dose." The Hospital argues that these terms have plain and ordinary meanings to those of ordinary skill in the art and need not be construed. DePuy disagrees and asks the Court to construe the terms as "an amount of radiation applied in a single treatment."

The dispute between the parties centers on whether a "radiation dose" can encompass more than one application of radiation to the implant. DePuy contends that it cannot. DePuy argues that the intrinsic evidence, especially several references to the terms in the specification, and common usage of the English language support their construction of the term as requiring a single dose of radiation above 5 Mrad to about 25 Mrad. The Hospital on the other hand argues that the plain meaning and intrinsic record establishes that the radiation dose claim term can encompass more than one treatment.

The Hospital points to the claim language itself, which does not specify the number of

radiation treatments allowable within the limits of the Patents suggesting that the number of treatments does not matter as long as the radiation dose meets the 5–25 Mrad requirement. Moreover, specification language, in the section entitled "Irradiation Steps," explicitly discloses irradiating the claimed implants using multiple treatments. *See* Doc. No. 147-1 at 10, 12:16–28 ("The irradiation for crosslinking and irradiation for sterilization steps may be performed separately (whether one precedes the other)."). DePuy takes issue with the Hospital's reliance on this statement in the specification arguing that the disputed claim terms relate only to the radiation dose for the purpose of crosslinking, not sterilization, and consequently conclude that a single crosslinking dose must meet the 5–25 Mrad requirement.

However, the disputed claim language is not that restrictive. DePuy specifically agrees that the article "a" before the words "radiation dose" allows for one or more radiation doses. Indeed, the Federal Circuit has confirmed such an interpretation stating that the use of the indefinite articles "a" and "an" typically mean "one or more." *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342 (Fed. Cir. 2008). Moreover, the claim terms must be considered in context. Claim 1 does not simply disclose a radiation dose of about 5–25 Mrad. The claim goes on to disclose "a radiation dose of above 5 Mrad to about 25 Mrad so as to crosslink the implant." Doc. No. 147-1 at 12, 16:46–49. Thus, the crosslinking element is the key to the dosage. Because crosslinking occurs with any type of radiation, a separate radiation treatment for the purpose of sterilization can also result in crosslinking consistent with the disputed claim terms. *See id.* at 13, 17:12–13 (Claim 7: "The method of claim 1, wherein the irradiation also sterilizes the implant."). Thus, the intrinsic evidence shows that the disputed claim terms are not limited to a single radiation treatment as DePuy suggests.

DePuy's argument, however, does not end there. DePuy goes on to argue that its construction in favor of a single radiation treatment is confirmed by language in the Hospital's '069 application. The relevant '069 claims—Claims 2, 10, 13–15—read as follows:

> 2. (New) A method for producing a wear-resistant and oxidation-resistant medical implant for a joint prosthesis comprising:
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> providing an oxidation-resistant orthopaedic material comprising a polyethylene;
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> forming the orthopaedic material into an implant for the joint prosthesis;
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> packaging the orthopaedic material after being formed into the implant;
>
> sterilizing the orthopaedic material while packaged; and
>
> irradiating the orthopaedic material during the method at a total radiation dose of above 5 Mrad to about 25 Mrad so as to crosslink the orthopaedic material, thereby improving its wear resistance, without thermally treating the orthopaedic material to extinguish free radicals in the orthopaedic material during or subsequent to irradiating the orthopaedic material, wherein the orthopaedic material contains an antioxidant rendering it resistant to oxidation caused by free radicals generated by the irradiation.
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> . . . .
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> 10. (New) The method of claim 2, wherein the total radiation dose is from above 5 Mrad to about 10 Mrad.
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> . . . .
>
> 13. (New) The method of claim 2 wherein the total radiation dose is delivered in time-separated stages.
>
> 14. (New) The method of claim 13 wherein a portion of the total radiation dose is delivered before the orthopaedic material is packaged and another portion of the total radiation dose is delivered after the orthopaedic material is packaged.

Doc. No. 147-16 at 5–6. DePuy contends that the addition of the word "total" in the '069 application limits the definition of "radiation dose" in the Patents to a single radiation treatment. In fact, DePuy alleges that the Hospital added the word "total" in the '069 application to expand the claims of the '710 and '347 Patents to include the cumulative effect of multiple doses of less than the 5–25 Mrad requirement thus demonstrating that the Hospital knew how to allow for

multiple radiation treatments but did not do so in the Patents.

DePuy also invokes the doctrine of claim differentiation to argue that the word "total" in the '069 application would be superfluous if the Patents allowed for more than a single radiation treatment. As such, DePuy asks the Court to construe the radiation dose terms in the Patents based on the language of the '069 application.

Admittedly, the doctrine of claim differentiation provides that "different claim terms are presumed to have different meanings." *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1382 (Fed. Cir. 2008). Thus, when construction of a claim term to mean the same thing as a separate claim term makes any claim term superfluous, the construction cannot stand as it clearly negates the significance of each different term. *Tandon Corp. v. U.S. Int'l Trade Comm'n*, 831 F.2d 1017, 1023–24 (Fed. Cir. 1987). Yet DePuy only cites to cases where the court applied the doctrine of claim differentiation to the construction of claims within a single patent, not claims in patent applications suggesting that reliance on claim language in the '069 application to construe the '710 and '347 Patents is misplaced.

Indeed, DePuy's proposed construction limiting the '710 and '347 Patents to a single radiation dose is specifically crafted to avoid making the word "total" in the '069 application superfluous. However, application of the doctrine of claim differentiation based solely on the word "total" in the '069 application is only appropriate in construing the '069 application itself, an exercise the Court has already refused to undertake. Had DePuy argued that a word within either the '710 or '347 Patent would be made superfluous by construing the disputed terms to disclose one or more radiation treatments, the claim differentiation doctrine might affect the claim construction. However, that is not what DePuy argued.

With that said, "[a] statement made during prosecution of related patents may be properly considered in construing a term common to those patents, regardless of whether the statement pre- or post-dates the issuance of the particular patent at issue." *Teva Pham. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1343 (Fed. Cir. 2015). Assuming that the "total radiation dose" claim term in the '069 application is just such a statement in the prosecution of a related patent, and as such, constitutes valid extrinsic evidence to be considered in the construction of the Patents at issue here, it still does not help DePuy. Indeed, "two claims which read differently can cover the same subject matter." *Id.* at 1023. Put another way, "claim drafters can . . . use different terms to define the exact same subject matter." *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006). Moreover, "[w]hether or not claims differ from each other, one can not interpret a claim to be broader than what is contained in the specification and claims as filed." *Tandon*, 831 F.2d at 1024. Here, DePuy has not shown that the terms in the Patents and the '069 application do not mean the same thing.

In addition, DePuy's citations to the intrinsic record do not support limiting the disputed claims terms to a single radiation dose. DePuy contends that the '710 and '347 specifications repeatedly reference "a radiation dose" or "the radiation dose" consistent with the terms' use in the claims. *See, e.g.*, Doc. No. 147-1 at 5, 1:62–64; 7, 6:58; 8, 7:3; 10, 12:1, 25–26, 36, 39–40, 51, 54–55; 11, 13:12–13. The Court agrees. The specification references are consistent with the "radiation dose" language in the claims. However, the specification references do not suggest a single radiation treatment. Instead, the Court finds that DePuy's specification references allow for multiple radiation treatments and therefore comport with the Hospital's construction.

Accordingly, DePuy has not convinced the Court to construe the terms "a radiation dose"

and "the radiation dose," as found in the '710 and '347 Patents, to limit the Patent to "an amount of radiation applied in a single treatment." Neither the intrinsic evidence nor the "total radiation dose" claim term in the '069 patent application support a single treatment limitation. Therefore, the Court rejects DePuy's proposed construction of the claim terms "a radiation dose" and "the radiation dose." The plain and ordinary meaning of both terms, as consistent with how a person of ordinary skill in the art would interpret these terms at the time of the invention, will govern as required going forward.

**3. "without thermally treating the implant to extinguish free radicals"**

DePuy contends that "without thermally treating the implant to extinguish free radicals" ("the Term"), found in Claim 1 of both the '710 and the '347 Patents, is indefinite under 35 U.S.C. § 112(b) because a person of ordinary skill in the art cannot determine what—in terms of temperature and duration—constitutes an excluded thermal treatment. DePuy explains that the line between what is and what is not a "thermal treatment to extinguish free radicals" defines the scope of the invention. As a result, DePuy argues that this line of demarcation must be defined clearly so that the fact-finder will ultimately be able to determine whether the prior art, or more specifically DePuy's allegedly infringing AOX product, is outside the scope of the Patents' claims. Alternatively, DePuy argues that the Court should construe the Term to mean "without exposing the implant to temperatures of 25 degrees Celsius or higher for at least two hours."

In response, the Hospital contends that the Term is not indefinite and does not require claim construction. The Hospital argues that a claim term need not be as specific as DePuy contends to survive an indefiniteness challenge. As such, the Hospital asserts that the phrase "to extinguish free radicals" sufficiently defines the excluded thermal treatments such that the Term

is not indefinite. In addition, the Hospital contends that the Term consists of straightforward language readily understood by those skilled in the art such that its plain and ordinary meaning should be used rather than DePuy's proposed claim construction based on temperature and duration. The Court agrees as discussed below.

**a. Indefiniteness**

Under 35 U.S.C. § 112(b), a patent specification must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention." Arising from Section 112(b), indefiniteness is an invalidity defense for which the accused infringer bears the burden of proof "by clear and convincing evidence." *Takeda Pharm. Co. v. Zydus Pharms. USA, Inc.*, 743 F.3d 1359, 1366 (Fed. Cir. 2014). A patent is invalid for indefiniteness only if "its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). Absolute precision is not required for a definite claim because "absolute precision is unattainable." *Id.* at 2129. A "modicum of uncertainty" is permissible so long as the patent claim provides "clear notice of what is claimed." *Id.* at 2128–29. Whether a patent claim's scope is reasonably clear is analyzed from the perspective of a person having ordinary skill in the relevant art at the time the patent application was filed. *Id.* at 2128.

Indefiniteness may be addressed at the claim construction stage. *See, e.g., Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1369 (Fed. Cir. 2014). A court may rely on expert testimony in determining whether a claim term is indefinite. *See, e.g., Datamize, LLC v.*

*Plumtree Software, Inc.*, 417 F.3d 1342, 1348 (Fed. Cir. 2005).

To succeed on its indefiniteness defense, DePuy must show by clear and convincing evidence that the disputed Term, "read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus*, 134 S. Ct. at 2124. In its attempt to meet this high burden, DePuy argues that (1) "without thermally treating to extinguish free radicals" does not have a plain and ordinary meaning to persons of ordinary skill in the art; (2) Dr. McKellop's "more than a trivial amount" construction mentioned during prosecution of the '710 and '347 Patents is indefinite; and (3) the "long-term oxidative stability" construction put forth by the Hospital's retained expert, Dr. Philip Noble, is indefinite.

DePuy asks the Court not to apply the Term's plain and ordinary meaning despite the Hospital's argument to the contrary. The Hospital contends that a person of ordinary skill in the art would understand the plain and ordinary meaning of the Term to be "not heating the implant to extinguish free radicals, *i.e.*, not heating the material or implant to a temperature and for a duration that is sufficient to extinguish free radicals by an amount that would impart long-term oxidative stability." Doc. No. 153 at 7 (citing Dr. Noble's Rebuttal Declaration). The Hospital cites Dr. Noble further in explaining that "long-term oxidative stability consists of at least a 5–10% increase in the oxidative stability of the material." *Id.* (citing Dr. Noble's deposition testimony).

DePuy's argument against the plain and ordinary meaning of the Term is quite brief and conclusory. DePuy simply states that the Term does not have a plain and ordinary meaning to a person of ordinary skill in the art. In addition, DePuy argues that applying the Term's plain and

ordinary meaning would not inform the trier of fact as to which thermal treatments are prohibited by Claim 1.

From this perspective, DePuy alleges that the Hospital's explication of the Term's plain and ordinary meaning is just as indefinite as the words used in the Term. Specifically, DePuy challenges the Hospital's reliance on Dr. McKellop's 2007 Declaration to the PTO Examiner about an amended claim term that ultimately became the Term as well as Dr. Noble's expert testimony explaining the Term, including his interpretation of Dr. McKellop's construction, to show that the Term is not indefinite. In his Declaration, Dr. McKellop stated that the Term "would be understood by the skilled artisan . . . to mean without heating the polyethylene to a temperature and for a duration that is sufficient to extinguish free radicals by more than a trivial amount." Doc. No. 147-9 at 6, ¶ 19. In his Rebuttal Declaration dated July 17, 2015, Dr. Noble explained Dr. McKellop's "more than a trivial amount" reference to mean "a trivial reduction in the concentration of free radicals . . . evidenced by a decrease in free radical concentration that does not impart long-term oxidative stability upon the material." Doc No. 130 at 20, ¶ 62. Answering counsel's questions about the meaning of Dr. McKellop's "more than a trivial amount" phrase at his deposition on August 5, 2015, Dr. Noble testified that skilled artisans would view oxidation resistance as a surrogate for measuring free radicals and that an improvement of 5–10% in oxidation resistance would constitute a non-trivial amount. Doc. No. 146-4 at 10–11, 198:21–199:11.

In its attempt to demonstrate that the "more than a trivial amount" construction is indefinite, DePuy relies upon its own retained expert, Dr. Cheryl Blanchard, who opined that

> a person of ordinary skill would have no understanding as to what is meant by "a trivial amount," or how much " more" is "more than a trivial amount." Nowhere

> in the claim or specification is "a trivial amount" defined in any way that would inform a POSA about its scope with reasonable certainty.

Doc. No. 147-12 at ¶ 75. Yet, "[c]laim language employing terms of degree has long been found definite where it provided enough certainty to one of skill in the art when read in the context of the invention." *Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374, 1378 (Fed. Cir. 2015). Claim terms that contain "some gray area regarding the scope of [the] terms . . . does not doom them as indefinite." *OpenTV, Inc. v. Apple, Inc.*, Case No. 14-cv-01622-HSG, 2015 WL 3544845, at *6–7 (N.D. Cal. June 5, 2015). Therefore, the key analysis is whether a person of skill in the art can determine the meaning of the claim language based on both the intrinsic evidence and their relevant expertise. *See Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1119 (Fed. Cir. 2002). Here, Dr. Blanchard's opinion is not persuasive in light of Dr. Noble's testimony, no less than thirteen times at his deposition, that a person of ordinary skill in the art readily understands what "by more than a trivial amount" means in the context of the Patents. *See* Doc. No. 153 at 8–9.

Dr. Noble's Rebuttal Declaration also confirms that persons of ordinary skill in the art in 2001 possessed the professional knowledge and expertise to analyze the results of a particular thermal treatment to determine whether free radicals were extinguished by more than a trivial amount. Dr. Noble stated:

> Based on the specification and prosecution history, a POSITA[5] would understand that the limitations means without heating the polyethylene to a temperature and for a duration that is sufficient to extinguish free radicals by more than a trivial amount. . . . In the context of these claims, a trivial reduction in the concentration of free radicals is evidenced by a decrease in free radical concentration that does not impart long-term oxidative stability upon the material.

[5]POSITA is Dr. Noble's acronym for "person of ordinary skill in the art."

Doc. No. 130 at 20, ¶ 62. In the same Declaration, Dr. Noble disagreed with Dr. Blanchard's indefiniteness analysis and opined that:

> In the context of these patents and applications, it is clear that a trivial amount refers to a reduction in free radicals that does not impart long-term oxidative stability on the implant . . . . [T]he art is replete with discussions of thermal treatment procedures utilized to extinguish or quench free radicals to make implants . . . have long-term oxidative stability.

*Id.* at 22, ¶ 64. Dr. Noble even cited two of Dr. Blanchard's own scholarly articles in support.

Dr. Blanchard's opinion aside, DePuy also argues that McKellop's "more than a trivial amount" construction is too nebulous to create the clear boundaries necessary to avoid indefiniteness based upon *S.O.I.TEC Silicon on Insulator Techs., S.A. v. MEMC Elec. Materials, Inc.*, 745 F. Supp. 2d 489, 509 (D. Del. 2010). In *S.O.I.TEC*, the court found the claim term "conducting a subsequent thermal annealing of the semiconductor material substrate at sufficiently low temperature to substantially limit diffusion of gas from the semiconductor material substrate" indefinite. *Id.* The court was persuaded because the claim did not identify a specific time, temperature, or gas or disclose any method for measuring the diffusion of gas or assessing the appropriate quantity of diffusion. *Id.* DePuy analogizes the *S.O.I.TEC* rationale to this case noting that the Term does not disclose how to measure free radicals, how many free radicals must be extinguished, or what constitutes "more than a trivial amount." Accordingly, DePuy asks the Court to find McKellop's construction indefinite like the court in *S.O.I.TEC* did when considering arguably similar and vague claim language.

Yet *S.O.I.TEC* is distinguishable. In *S.O.I.TEC*, the district court was presented with minimal if any compelling extrinsic evidence to assist in its claim construction. *Id.* at 508–09. Here, there is extrinsic evidence that demonstrates that a person of ordinary skill in the art, as of

2001, would have known how to measure UHMWPE to determine whether a given thermal treatment had extinguished free radicals by more than a trivial amount even without any express recitation of methods or specific measurements. As already discussed, Dr. Noble demonstrated knowledge of such methods among skilled artisans—even DePuy's own expert, Dr. Blanchard. Dr. Noble also testified that skilled artisans would use oxidation resistance as a surrogate measure of a trivial amount of free radicals and that a 5 to 10 percent improvement in oxidation resistance, constituting long-term oxidative stability, would be a non-trivial amount. Doc. No. 146-4 at 10–11.

Nevertheless, DePuy urges the Court to discount Dr. Noble's "long-term oxidative stability" construction cited by the Hospital. Doc. No. 153 at 7 (citing Dr. Noble's deposition testimony) ("long-term oxidative stability consists of at least a 5–10% increase in the oxidative stability of the material."). DePuy argues that as extrinsic evidence, Dr. Noble's construction contradicts intrinsic evidence and creates rather than alleviates indefiniteness. Indeed, "a court should discount any expert testimony that is clearly at odds with the claim construction mandated by the" intrinsic evidence. *Phillips*, 415 F.3d at 1318. "[E]xtrinsic evidence may be used only to assist in the proper understanding of the disputed limitation; it may not be used to vary, contradict, expand, or limit the claim language from how it is defined, even by implication, in the specification or file history." *Bell Atl. Network Servs. v. Covad Comm'cns Grp.*, 262 F.3d 1258, 1269 (Fed. Cir. 2001). In addition, when a claim includes deliberately vague language from which an expert is unable to determine what falls within a claim, the claim and patent are indefinite. However, DePuy simply has not persuaded the Court that Dr. Noble's opinion and deposition testimony contradict the intrinsic evidence or create indefiniteness.

For instance, DePuy finds inconsistency between Dr. Noble's inability during his deposition to ascertain whether the thermal treatments found in the prior art, especially Poggie and Streicher, would fall within the scope of the Term as compared to Dr. McKellop's Declaration in the prosecution history stating that both the Poggie and Streicher annealing treatments fell outside the scope of the Term because they taught that orthopaedic material should be thermally treated to extinguish free radicals. In making this argument, however, DePuy ignores key parts of Dr. Noble's testimony.

While Dr. Noble was unable to opine at his deposition about whether the Poggie and Streicher thermal treatments would fall within the scope of the Term, he did testify that he would have been able to determine whether Poggie constituted a thermal treatment to extinguish free radicals if he could have considered free radical data related to the particular thermal treatment. Such data was simply unavailable to him at his deposition. His testimony indicates that he has the skills, or knows how, to go about determining whether the Poggie treatment, or any other thermal treatment for that matter, extinguishes free radicals given the proper data. Accordingly, a person of ordinary skill in the art could also determine whether a particular thermal treatment fell within the scope of the Term if given the proper free radical data. Dr. Noble's approach confirms the Hospital's conclusion that the key to the plain and ordinary meaning of "without thermally treating to extinguish free radicals" is the phrase "to extinguish free radicals," not "thermally treating." DePuy, on the other hand, erroneously focuses its indefiniteness defense on defining the relevant thermal treatments by temperature and duration despite the intrinsic evidence, Dr. Noble's opinion, and his deposition testimony, which establish that the defining characteristic of a relevant thermal treatment is the extinguishing of free radicals.

DePuy also suggests that Dr. Noble's testimony equates "long-term oxidative stability" solely with irradiated and remelted polyethylene. DePuy finds this inconsistent with the prosecution history in which both annealing and remelting were found to constitute prohibited thermal treatments. Yet, DePuy's conclusion here is not consistent with the full context of Dr. Noble's testimony either. Dr. Noble defined "long-term oxidative stability," as evidence of extinguishing free radicals, based on a 5–10% increase in the oxidative stability of annealed polyethylene and compared it to the higher level of oxidation resistance that would result from remelting. Dr. Noble never limited "long-term oxidative stability" to remelting. As such, Dr. Noble's opinion does not contradict the intrinsic evidence and need not be discounted.

DePuy also criticizes Dr. Noble's testimony where, for the first time, he opined that a 5–10% improvement in oxidation resistance constituted a non-trivial amount of extinguished free radicals. DePuy contends that this standard, which is not included in the intrinsic evidence but yet is relied upon by the Hospital to support its argument for the plain and ordinary meaning of the Term, improperly expands the definition of the Term. DePuy also challenges the reliability of the 5–10% rate because Dr. Noble based it solely on his personal observations from "noise in the data" rather than the intrinsic evidence or other prior art, for instance. DePuy's conclusions, however, are not consistent with the context of Dr. Noble's testimony.

No one disputes that the 5–10% reference surfaced for the first time during Dr. Noble's testimony. Specifically, it arose as Dr. Noble answered questions about what he considered an inconsequential difference in long-term oxidative stability and a non-trivial amount of free radicals. Doc. No. 147-11 at 44, 52; 166:6–15;198:21–22. Nevertheless, Dr. Noble's testimony about the 5–10% improvement rate did not expand the definition of the Term as DePuy

contends. Rather, Dr. Noble's reference to the improvement rate demonstrated his understanding, as a person of ordinary skill in the art, of the phrases presented to him in the deposition. Moreover, a person of ordinary skill in the art like Dr. Noble would be better equipped than anyone to interpret noise in the data. As such, the context surrounding Dr. Noble's testimony about the 5–10% improvement rate demonstrates further that a person of ordinary skill in the art would understand how to identify a thermal treatment to extinguish free radicals if presented with sufficient information.

In summary, to succeed on its indefiniteness defense, DePuy must show by clear and convincing evidence that the disputed Term, "read in light of the specification delineating the patent, and the prosecution history, fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus*, 134 S. Ct. at 2124. Or more specifically, DePuy must present clear and convincing evidence that a person of ordinary skill in the art could not understand the claim term, "without thermally treating to extinguish free radicals," with reasonable certainty based on the claim language, the specification, the prosecution history, and professional expertise. DePuy simply has not carried its high burden to show that the claim term is indefinite sufficient to invalidate the Patents.

**b. Claim Construction**

Having found that "without thermally treating to extinguish free radicals" is not indefinite, the Court now considers DePuy's alternative request to, at a minimum, construe the claim term to prohibit exposing implants to temperatures of 25°C or higher for at least two hours. DePuy cites Dr. McKellop's 2007 Declaration to the PTO examiner as well as other existing patents, which were referenced in the specification and prosecution history, to show that

the Hospital disclaimed annealing and remelting defined by the lower limits of 25°C for at least two hours. "[W]here the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." *Omega Eng'g*, 334 F.3d at 1324. A patentee "cannot recapture claim scope [during claim construction that was] disavowed during prosecution to prove infringement." *Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1379 (Fed. Cir. 2008). Furthermore, DePuy cites Dr. Noble's testimony that thermal treatments exposing an implant to 25°C or higher or heating implants for as little as two hours would be excluded from the scope of the Patents.

Based on this evidence and more, the Hospital would likely agree that generally speaking thermal treatments at 25°C or higher for two hours or more would be outside the scope of the Term. Arguably, the Hospital would sacrifice nothing if such thermal treatments were expressly excluded. The problem, however, is that such a construction would be incomplete. The Term defines the excluded thermal treatments based on how they extinguish free radicals, not based strictly on temperature and duration. As discussed above, persons of ordinary skill in the art are capable of determining whether free radicals have been extinguished by a particular thermal treatment. Accordingly, they can determine whether a specific thermal treatment is excluded even if it involves temperatures lower than 25°C for less than two hours.

Therefore, because the Court is convinced that the plain and ordinary meaning of "without thermally treating to extinguish free radicals" was understood by persons of ordinary skill in the art at the time of the patent application in the context of the claim language itself, the specification, and prosecution history, the Court rejects DePuy's proposed construction and the

plain and ordinary meaning of the Term will apply in this litigation going forward.

## V. CONCLUSION

As discussed above, precedent does not exist to support the construction of claims in patent applications. Therefore, the Court construes only the claim terms (1) "medical implant" or "implant," as included in Claim 1 of the '710 and '347 Patents and Claim 12 of the '347 Patent; (2) "a radiation dose," as included in Claims 1 and 16 of both Patents, or "the radiation dose," as included in Claim 2 of both Patents; and (3) "without thermally treating to extinguish free radicals," as included in Claim 1 of both Patents. Review of the patent claims, the specifications, the prosecution histories including Dr. McKellop's Declaration to the PTO Examiner, and extrinsic evidence including but not limited to the parties' expert opinions reveals that all three claim terms carry a plain and ordinary meaning understandable by persons of ordinary skill in the art. Therefore, claim construction is not necessary. Furthermore, DePuy has not shown, by clear and convincing evidence, that "without thermally treating to extinguish free radicals" is indefinite.

With this order, the deadlines defined in Local Patent Rules 5-1 and 6-1 are now triggered as to the patent issues raised in this consolidated action. As discussed before this Court on September 1, 2015, the Court also **SETS** a Telephonic Status Conference for **January 25, 2016**, at **10:30 a.m. (E.S.T.)** for the purpose of establishing all other necessary discovery and motion deadlines, including those related to the remaining contract liability issues. *See* Doc. No. 149 at 1. The Court will call all counsel listed on the docket sheet unless it is notified that specified attorneys need not be contacted. If, at the time of the scheduled conference, any participating attorney will not be at the telephone number identified on the docket, please contact

chambers at 574-246-8100.

**SO ORDERED.**

Dated this 8th day of January, 2016.

S/Christopher A. Nuechterlein
Christopher A. Nuechterlein
United States Magistrate Judge